UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,720	02/15/2001	Klaus Abraham-Fuchs	P00,1222	2613

26574 7590 01/18/2007

SCHIFF HARDIN, LLP
PATENT DEPARTMENT
6600 SEARS TOWER
CHICAGO, IL 60606-6473

EXAMINER	
MORAN, MARJORIE A	
ART UNIT	PAPER NUMBER
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

TH

Office Action Summary	Application No.	Applicant(s)	
	09/784,720	ABRAHAM-FUCHS ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-8 and 10-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8 and 10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1-8 and 10-18 are pending. Applicant is thanked for clarifying the claim status in the reply filed 10/30/06. rejections not reiterated below are hereby withdrawn in view of the claim amendments filed 10/30/06.

Claim Rejections - 35 USC § 112

Claims 4, 6, 7, 10-16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 4 recites "expert evaluation is programmed and trained to use system automatically said measurement protocol" which is both grammatically incorrect and nonsensical. The term "system" appears to be misplaced, and one or more terms seem to be missing. As it is unclear what limitation is intended, the claim is indefinite. For purposes of further examination, the claim is interpreted to be limiting an expert evaluation system to be one capable of "automatically" using (?) a measurement protocol.

Amended claim 6 recites that an expert evaluation system is ...trained to devise measurement protocols is for a specific pathology...: which is grammatically incorrect and confusing. It is unclear whether applicants intend a system which is programmed and trained to devise measurement protocols for a specific pathology, or whether applicant intends a system which is trained to devise protocols and wherein the system IS one "for" a specific pathology (i.e. the system is dedicated to detect only that

pathology by testing biomolecular markers). As the limitation intended is unclear, the claim is indefinite.

Claim 7 depends from claim 6 and fails to correct the indefiniteness of claim 6, and is therefore also indefinite.

Applicant's arguments with respect to claims 4, 6, and 7 have been considered but are moot in view of the new ground(s) of rejection set forth above.

Claim18 recites the term "improved" in the last paragraph. The term "improved" in claim18 is a relative term which renders the claim indefinite for reasons previously set forth. In the response filed 10/30/06, applicant argues that the claim amendment overcomes the rejection. In response, it is noted that the claim still recites the term, and nowhere does applicant define or otherwise state what is intended by an "improved" diagnostic value. As the metes and bounds *intended by applicant* for this term are still unclear, the examiner maintains that the claim is indefinite, and the rejection of claim 18 and its dependent claims is maintained.

Claim Rejections - 35 USC § 103

Claims 2-7, 10-15, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over BARNHILL et al (US 6,248,063, filed 7/25/1995) in view of WRIGHT, JR (US 2004/0018519, filed 11/20/2000).

Claims 17 and 18 are directed to a network (system product) and a method of use of the network product wherein the network comprises a plurality of biochips, each comprising multiple biomolecular markers and a patient sample, a plurality of point of

care devices at a plurality of sites wherein each point of care device is capable of receiving a biochip and performing diagnostic testing on the sample to obtain raw point of care data, an expert system into which the raw data is entered and which produces a diagnostic result, a plurality of patient records for each patient, a plurality of point of care entry stations comprising means for entering follow-up diagnostic data, a remote server and evaluation station wherein the remote server comprises data links to the point of care test devices and electronic patient records, and an evaluation system comprising a computer which uses all of the point of care raw data and the diagnostic data as a training set to correlate a further marker with a different medical condition than that associated with the diagnostic result.

Claims 2 and 10 limit the creation of a modified expert rule to creating one for devising a measurement protocol. Claims 3 and 11 limit the measurement protocol to be one for a selected pathology. Claims 4 and 12 limit the creating of a modified rule to be automatic. Claims 5 and 13 limit the network to comprise a memory comprising a plurality of measurement protocols and limit the point of care device to one capable of accessing the memory to obtain a selected measurement protocol. Claims 6 and 14 limit the measured protocol to be one for a specific pathology and to employ a predetermined number of biomolecular markers. Claims 7 and 15 limit the biochips to be sensitive for more markers than are predetermined, such that augmented testing data may be obtained and included in the point of care data. Claim 8 limits the point of care data entry stations to comprise means for entering patient history data and characterization of result as false positive, false negative or correct. Claim 16 limits ht

method to one further comprising obtaining follow-up data and indicating whether a test result is a false positive, a false negative or correct.

BARNHILL teaches a system and method for receiving patient data from a remote location (point of care), analyzing the data and producing a diagnostic value (abstract). BARNHILL teaches collecting patient data, including electronic patient records, inputting the data into a neural network (remote server with evaluation system), and creating a "modified expert rule" (i.e. trained neural net) for diagnosing any of a variety of diseases, such as osteoporosis or cancer (col. 7, line 39-col. 9, line 53). BARNHILL specifically teaches that diagnostic data including data from a variety of markers may be added to other raw input variables to provide a final diagnostic index (col. 13, line 60-col. 14, line 10). BARNHILL specifically teaches that an output value from a first neural network (expert system) and a SECOND set of diagnostic markers are sent to a second trained neural network to make a diagnosis (col. 13, lines 53-60). BARNAHILL specifically exemplifies that different markers from the same assay may be used to diagnose three different conditions; i.e. BPH vs. prostate cancer vs. normal (col. 8, lines 27-37 and vol. 10, liens 51-58). BARNHILL teaches that concentrations of biomarkers are determined for a patient (col. 13, lines 11-14), and teaches that his system comprises diagnostic devices comprising sample collection means and sample detecting means (col. 14, lines 55-63), but does not specifically teach a biochip or measurement protocols.

WRIGHT teaches an integrated system and method for diagnosing prostate cancer comprising a biochip comprising prostate cancer markers, various measurement

protocols, and a computer comprising instructions for determining correlations between the markers and diagnosis (abstract and para's 26 and 28). WRIGHT teaches that his biochips may comprise more markers than the "predetermined" ones of PSMA and PSMA' (para's 76- 78). WRIGHT teaches that his computer instruction for diagnosis may include a neural network (para 20).

It would have been obvious to one of ordinary skill in the art at the time of invention to have used the biochips and measurement protocols of WRIGHT in the system and method of BARNHILL where the motivation would have been to accurately diagnose prostate cancer and BPH using a combination of biomarkers and computer algorithms, as taught by both BARNHILL and WRIGHT.

Applicant's arguments filed 10/30/06 have been fully considered but they are not persuasive. In response to the argument that BARNHILL and WRIGHT do not teach use of "hidden" markers or markers which are "kept track of" and used in combination with "follow-up" information, it is noted that the claims do not recite hidden markers nor "keeping track" of theoretically unknown markers. While amended claims 17 and 18 do recite using follow-up diagnostic data in combination with point of care data as a training data set that correlates a "further" biomarker with a different disease than one previously diagnosed, the claims do not recite a combination of hidden markers and follow-up information to diagnose a disease not formerly recognized to be present in a patient. In fact, BARNHILL does teach that different biomarkers correlated to different diseases may be evaluated in the same assay, as set forth above, and teaches biomarkers are to be preprocessed prior to being sent to an "expert system" along with

demographic/other diagnostic data in order to diagnose a disease, as set forth above, thus BARNHILL makes obvious correlation of different biomarkers with different diseases using biomarkers from a single assay.

For these reasons and those previously set forth, the examiner maintains that BARNHAILL and WRIGHT make obvious the claimed system and method, and therefore maintains the rejection.

Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over BARNHILL et al (US 6,248,063, filed 7/25/1995) in view of WRIGHT, JR (US 2004/0018519, filed 11/20/2000).as applied to claims 2-7, 9-15, and 17-18 above, and further in view of KULIKOWSKI et al. (Proc. Of ACM Conference on History of Medical Informatics. Dec. 1987, pp. 199-206).

In the response filed 10/30/06, applicant merely argues that KULIKOWSKI does not remedy the argued deficiencies of BANRHILL and WRIGHT. In response, it is noted that the examiner maintains the rejection over BARNHILL and WRIGHT, and therefore also maintains the rejection over the combination of BARNHILL and WRIGHT with KULIKOWSKI.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Monday-Friday; 6 am-2:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
1/8/07